

REMARKS/ARGUMENTS

Status of the Claims

Claims 52-107 will remain pending in the application. Claims 54, 56, 57, 74, 76, 92, 93, 95 and 96 are amended as set forth above. The corrections to the chemical formulas in the specification and in the claims are made to correct errors typographical errors where the "N" in the original specification on page 16 in the three chemical formulas were mistakenly printed as "H" in the published application. Also attached is U.S. Patent No. 5,855,940, the parent application, which correctly printed the above chemical structures. Additionally, the claims are amended to correct the tetra-alkylalicyclic ammonium salt to remove the inadvertent insertion of "H₂" with the "N" in the ring. The original specification and the '940 patent show that this is an inadvertent error. No new matter has been added.

Claim Rejections - 35 U.S.C. § 102

Claims 52, 82-84, 86-87, 102-103 and 107 are rejected by the Examiner under 35 U.S.C. § 102 (e) as being anticipated by Smith et al. (U.S. Patent No. 5,414,124). Applicants respectfully request reconsideration and withdrawal of the rejection.

In order for a reference to anticipate the claimed invention, the cited reference must disclose each and every limitation of the claimed invention. The Examiner asserts that Smith et al. disclose germicidal compositions comprising about 50-80% of a quaternary ammonium compound in 48-84% propylene glycol and water for the remainder. In contrast, the compounds of claims 52, 82-84 and 86-87 comprise a quaternary ammonium compound with a concentration from greater than about 15% by weight to about 40% by weight or about 40% by weight. Also in contrast, claims 102-103 and 107 comprise a quaternary ammonium compound with a concentration of up to about 1% by weight or of about 0.01% to about 1% by weight. Therefore, the concentration of quaternary ammonium compound in the compounds of claims 52, 82-84, 84-86, 102-103 and 107 is outside of the range disclosed by Smith et al. In other words, Smith et al. fails to disclose that the composition comprises a quaternary ammonium compound within the ranges of recited in claims 52, 82-84, 84-86, 102-103 and 107. It is unclear to applicants how the Examiner can interpret the teachings of

Smith et al. to encompass the ranges of the claimed quaternary ammonium compound because Smith et al. only disclose a 50% or a 80% quaternary ammonium compound. Because Smith et al. fails to disclose each and every limitation of the claimed invention, the claimed invention is not anticipated by Smith et al.

Claim Rejections - 35 U.S.C. § 103

**A. Rejection Of Claims 53-61, 65-81, 85 And 90-101
Under 35 U.S.C. § 103 As Being Unpatentable Over Smith Et
Al. In View Of Gauvreau**

Claims 53-61, 65-81, 85 and 90-101 are rejected by the Examiner under 35 U.S.C. § 103 as being obvious over Smith et al. in view of Gauvreau. As in the lack of novelty rejection discussed above, the Examiner asserts that Smith et al. discloses germicidal compositions comprising about 50-80% of a quaternary ammonium compound in 48-84% propylene glycol and water for the remainder, but does not disclose that the quaternary ammonium compound is an alkylpyridinium salt, a tetra-alkylammonium salt, or an alkylalicyclic ammonium salt. However, the Examiner asserts that since Gauvreau teaches inclusion of cetyl pyridinium in the disclosed disinfecting compositions and that Smith that does not disclose cetyl pyridinium, it would have been obvious for a person of ordinary skill in the art to either include cetyl pyridinium in the composition of Smith et al. or to substitute cetyl pyridinium for the quaternary ammonium compounds of Smith et al. Applicants respectfully request reconsideration and withdrawal of the rejection.

With respect to claims 53, 54, 59, 69-72, 75-81, 85, 90, 94, 95 and 97-101, these claims are not obvious over the combined disclosures of Smith et al. and Gauvreau because the combined disclosures of Smith et al. and Gauvreau do not teach each and every limitation of the claims. As discussed above, Smith et al. teaches a composition comprising about 50-80% of a quaternary ammonium compound. Smith does not teach a composition comprising greater than about 15% by weight to about 40% by weight of a quaternary ammonium compound, as recited in claims 52 (upon which claims 53, 54, 59, 77, 80, 81, and 90 depend), 75 and 76. Smith does not teach a composition comprising greater than about 10% to about 40% of a quaternary ammonium compound, as recited in claims 69 and 70. Smith does not

teach a composition comprising greater than about 10 to about 30% of a quaternary ammonium compound, as recited in claims 71 and 72. Smith does not teach a composition comprising greater than about 15 to about 25% of a quaternary ammonium compound, as recited in claims 77-79. Smith does not teach a composition comprising a quaternary ammonium compound with a concentration of about 40% by weight, as recited in claim 82, upon which claim 85 depends. Additionally, Smith does not teach a composition comprising a quaternary ammonium compound with a concentration of up to about 1% by weight, as recited in claim 94, upon which claim 95 depends or a composition comprising a quaternary ammonium compound with a concentration of up to about 0.01% to about 1% by weight, as recited in claim 97, upon which claims 98-101 depends. Gauvreau does not cure the deficiencies of Smith et al which do not teach the claimed concentration ranges of claims 53, 54, 59, 69-72, 75-81, 85, 90, 94, 95 and 97-101, and therefore, these claims are not obvious over Smith et al. in view of Gauvreau.

Turning to claims 55-58, 60, 61, 65-68, 73, 74, 91-93 and 96, the Examiner has failed to establish a *prima facie* case of obviousness. A proper rejection for obviousness under §103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition, or device, or carry out the claimed process and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. [emphasis added] *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438 (Fed. Cir. 1991).

Neither Smith et al. nor Gauvreau would have suggested to a person of ordinary skill in the art to either include cetyl pyridinium in the composition of Smith et al. for an additive disinfecting effect or to substitute cetyl pyridinium for the quaternary ammonium compounds of Smith et al. As stated in Gauvreau. column 2, lines 35-43, the composition of Gauvreau comprises the following two active constituents: (a) a halide salt of a pyridinium compound and (b) a member of the group of organic compounds all having ten carbon atoms consisting of the terpenes and their oxygenated derivatives. Gauvreau discloses the synergistic effects

that are achieved when these two active constituents are combined in one composition. For example, column 6, lines 23-28 of Gauvreau state "the admixture of the two ingredients produces an improvement in antimicrobial activity which in some cases is more than a thousand times that of either constituent alone. This clearly demonstrates that a strong synergistic potentiation is achieved." Gauvreau provides data showing the improvements of antimicrobial activity for a combination of cetyl pyridinium halide salts with various monoterpenes as compared to the separate antimicrobial activity for each compound. *See* Tables III and IV of Gauvreau. The synergistic effects disclosed by Gauvreau for the combination of a cetyl pyridinium halide salt and a terpene would have motivated a person of ordinary skill in the art to make antimicrobial compositions comprising both cetyl pyridinium and a terpene. However, a person of ordinary skill in the art would not have been motivated to make an antimicrobial composition containing cetyl pyridinium yet not containing a terpene. Therefore, it would not have been obvious to a person of ordinary skill in the art to either include cetyl pyridinium in the composition of Smith et al. for an additive disinfecting effect or to substitute cetyl pyridinium for the quaternary ammonium compound of Smith et al. because the compounds of Smith et al. do not contain a terpene.

Furthermore, as discussed above, Gauvreau discloses the synergistic effects of a composition comprising two active constituents, a halide salt of a pyridinium compound and a terpene. Because the composition of Smith et al. does not contain a terpene, a person of ordinary skill in the art would not have had a reasonable expectation of success in including cetyl pyridinium in the composition of Smith et al. or substituting cetyl pyridinium for the quaternary ammonium compound of Smith et al. As discussed above, Gauvreau discloses the synergistic effects of a composition comprising two active constituents, a halide salt of a pyridinium compound and a terpene.

B. Rejection Of Claims 62, 89 and 104-106 Under 35
U.S.C. § 103 As Being Unpatentable Over Smith Et Al. In
View Of The Merk Index

Claims 62, 89 and 104-106 are rejected by the Examiner under 35 U.S.C. § 103 as being obvious over Smith et al. in view of the Merk Index. Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner asserts that Smith et al. discloses germicidal compositions comprising about 50-80% of a quaternary ammonium compound in 48-84% propylene glycol and water for the remainder, but does not disclose glycerol as a solvent for quaternary ammonium compounds. However, the Examiner asserts that since the Merk Index teaches that propylene glycol and glycerol are substitutes for each other, it would have been obvious for a person of ordinary skill in the art to combine propylene glycol and glycerol with the expectation of the solvents have an additive effect.

Claims 62, 89 and 104-106 are not obvious over the combined disclosures of Smith et al. and the Merk Index because the combined disclosures of Smith et al. and the Merk Index do not teach each and every limitation of the claims. As discussed above, Smith et al. teaches a composition comprising about 50-80% of a quaternary ammonium compound. Smith does not teach a composition comprising greater than about 15% by weight to about 40% by weight of a quaternary ammonium compound, as recited in claim 52, upon which claims 62 and 89 depend. Additionally, Smith et al. does not teach a composition consisting essentially of a quaternary ammonium compound with a concentration of up to about 1% by weight, as claimed in claim 102, upon which claims 104-106 depend. The Merk Index does not cure the deficiencies of Smith et al. Because the combined disclosures of Smith et al. and the Merk Index do not teach each and every limitation of claims 62, 89 and 104-106, the claimed invention is not obvious over Smith et al. in view of the Merk Index.

Applicants disagree with the Examiner's rejection of claims 62, 89 and 104-106 as being obvious over Smith et al. in view of the Merk Index for the reasons discussed above. However, assuming, *arguendo*, that the combined disclosures of Smith et al. and the Merk Index did disclose each and every limitation of the claimed invention, the present invention is not obvious over Smith et al. in view of the Merk Index because, in contrast to the Examiner's assertion that propylene glycol and glycerol are substitutes for each other, the solubility, foam dispersion and miscibility of the quaternary ammonium compound of the present invention in propylene glycol are superior as compared to the same properties in glycerol.

The choice of propylene glycol was not a mere selection or design choice, but rather, propylene glycol was chosen for its particular and unexpected properties as a solvent of quaternary ammonium compounds in the solutions of the present invention. In support of the particular usefulness of propylene glycol, and thus the choice of propylene glycol in the claimed solution as compared to glycerol, the Examiner is referred to the attached Declaration Under 37 C.F.R. § 1.132 by Dr. Kelly W. Beers (Appendix A), which compares the solubility, foam dispersion and miscibility of cetylpyridinium chloride (CPC) in propylene glycol (PG), to the same properties for ethanol and glycerol.

As illustrated in the Declaration, PG was responsible for a 2-4 fold more concentrated solution of CPC to stay in solution with no further manipulations as compared to CPC solution in glycerol as the solvent. Further, less foam was generated when spraying the solution of CPC diluted from the claimed concentrate prepared with PG as compared to glycerol, which is an important property in regard to using the dilute solution to spray food products, where effectively covering the food surface is important in increasing the effectiveness of the solution for reducing microbial contamination. Additionally, the data shows that a 2-fold higher concentration of CPC was more easily miscible in a solution containing PG than in a comparable solution containing glycerol, which is important for preparing homogenous solutions from the concentrated quaternary ammonium compound solutions. Based upon all of these arguments, withdrawal of this rejection is respectfully requested.

C. Rejection Of Claim 88 Under 35 U.S.C. § 103 As Being
Unpatentable Over Hall In View Of Vidra and Further In View
of The Merk Index

Claim 88 is rejected by the Examiner under 35 U.S.C. § 103 as being obvious over Hall in view of Vidra and the Merk Index. The Examiner asserts that Hall teaches a mouth rinse comprising about 10% of a quaternary ammonium compound in a solvent comprising propylene glycol. Hall does not teach a composition comprising greater than about 15% by weight to about 40% by weight of a quaternary ammonium compound, as recited in claim 52 from which claim 88 depends. The Examiner further asserts that Vidra teaches solvent formulations for quaternary ammonium compounds comprising glycerol and ethyl alcohol.

Finally, the Examiner asserts that the Merk Index teaches that glycerol and propylene glycol are equivalents. The Examiner concludes that it would have been obvious for a person of ordinary skill in the art to combine ethanol in the formulation of Hall. Applicants respectfully request reconsideration and withdrawal of the rejection. Vidra and the Merk Index do not cure the deficiencies of Smith et al.

Applicants disagree with the Examiner's rejection of claim 88 as being obvious over Hall in view of Vidra and further in view of the Merk Index for the reasons discussed above. However, assuming, *arguendo*, that the combined disclosures of Hall, Vidra and the Merk Index did disclose each and every limitation of the claimed invention, the present invention is not obvious over Hall in view of Vidra and further in view of the Merk Index because, for the reasons discussed above, the solubility, foam dispersion and miscibility of the quaternary ammonium in the compound of the present invention in propylene glycol are superior as compared to the same properties in ethanol (see Declaration of Dr. Kelly W. Beers in Appendix A). Furthermore, as shown in the attached Declaration of Dr. Kelly W. Beers, PG was responsible for a 2-4 fold more concentrated solution of CPC to stay in solution with no further manipulations as compared to CPC solution in ethanol as the solvent. The Declaration also notes that ethanol could not be tested and compared for foam dispersion and miscibility because the CPC precipitated out of solution prior to performing these tests. Additionally, the negative aspects of using ethanol as a solvent because it is flammable and emits noxious vapors, militates against its use as a solvent system. Based upon the above arguments, it is requested that this rejection be withdrawn.

CONCLUSION

As the above-presented amendments and remarks address and overcome all of the rejections presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested.

If the Examiner has any questions concerning this application, he or she is requested to contact the undersigned.

Respectfully submitted,

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